IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: LIVELY *et al.*

Title: **NUCLEIC ACID COATED PARTICLES**

Appl. No.: 10/529,010

Examiner: Robert M. KELLY

Art Unit: 1633

Confirmation Number: 8892

DECLARATION OF DR. PHIL WHITE UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Phil White, hereby declare and state as follows:

1. I currently hold the position of Group Head, Formulation and Analytical Development, Vaccine Research of PFIZER, INC., the present owner of the captioned application.

2. I have been employed by Pfizer since July 2008 as a group head, responsible for formulation development within the vaccine research group and I am responsible for the development and characterization of research vaccine formulations. I was previously employed by PowderMed Ltd for 4 years as group head of process sciences with responsibilities for development, manufacturing and release of PMED™ gold formulations and clinical active pharmaceutical ingredient (plasmid DNA). I hold a PhD from Oxford Brookes University in molecular microbiology and analytical development.

3. I will not receive and remuneration from the commercialization of a product or technology related the invention of the present application.

4. I have reviewed:

(A) U.S. Appl. No. 10/529,010 (the '010 application) (U.S. Publ. No. 2006/0153804) entitled NUCLEIC ACID COATED PARTICLES, which the inventors filed as a PCT application on September 29, 2003, based on a U.S. provisional application filed on September 27, 2002;

(B) the "Listing of Claims" in an Amendment and Reply submitted on August 7, 2009, to the U.S. Patent & Trademark Office (USPTO) by the inventors during prosecution of the '010 application; and

(C) an Examiner's Office Action dated October 22, 2009, mailed by the USPTO during prosecution of the '010 application.

5. After reviewing the '010 application, the August 7, 2009 Amendment and the October 22, 2009 Office Action, I understand that the Examiner has raised a rejection relating to the phrase "wherein the particles suitable for delivery have a half life of at least 27 days at 40°C", which is present in independent claims 1, 25 and 67. Specifically, I understand that the Examiner has asserted that the '010 application specification did not describe this phrase "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession" of the presently claimed particles and methods for obtaining them. *See* Office Action, paragraph spanning pages 7-8.

6. I also understand that because the inventors added the phrase "wherein the particles suitable for delivery have a half life greater of at least 27 days at 40°C" to claims 1, 25 and 67 by amendment during prosecution, the Examiner considers this phrase to be "new matter." As I understand it, the Examiner consider this phrase to be "new matter" because he believes that this aspect of the present invention was not adequately described in the '010 application as filed.

7. A review of the specification, and Example 4 in particular, in the '010 application indicate to me that Example 4 describes the production of DNA coated gold particles using several reagents that result in the precipitation of DNA onto gold particles. The reagents used in Example 4 include a tetraarginine homopolymer (*i.e.*, 4 arginine amino acids), EDTA or DTPA as a metal chelating agent, and sucrose or trehalose as a sugar. As indicated in Example 4, the inventors tested the long term stability, i.e., the half-life, of particles produced using various permutations of these ingredients at 25°C and 40°C. *See* U.S. Publ. No. 2006/0153804, [0192] – [194].

8. As seen in Table 2 in Example 4 of the '010 application, particles produced by three of the four different DNA precipitation formulations had a half-life of at least 27 days at 40°C. In particular, at 40°C, Formula "TA101.2" (DNA + TetraArg + DTPA + sucrose) had a half life of 27 days, Formula "TA101.1" (DNA + TetraArg + EDTA + sucrose) had a half life of 65 days, and Formula "TA101.3" (DNA + TetraArg + EDTA + trehalose) had a half life of 59 days.

9. Thus, to scientists skilled in the technology of preparing metal carrier particles coated with DNA in 2002 or 2003, data disclosed in Table 2 of the '010 application expressly described DNA coated-particles produced using formulations containing an arginine homopolymer, a metal chelating agent and a sugar. Table 2 also expressly described that such particles, such as those obtained in the presence of, *inter alia*, EDTA and/or sucrose, had a half-life of 27 days or greater, i.e., "at least 27 days."

10. It is my opinion, therefore, that a knowledgeable person, informed by the data presented in Table 2, would have understood that the inventors of the '010 application realized that they had prepared relevant particles having a half-life of at least 27 days at 40°C.

11. Accordingly, it is also my opinion that the phrase "wherein the particles suitable for delivery have a half life of at least 27 days at 40°C" is clearly described in the specification of the present application and, therefore, the inventors "had possession" of the invention at the time of filing.

12. I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 22-MAR-2010 By 

Dr. Phil White